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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,789	04/15/2004	Douglas A. Hettrick	P-10880.00	6661

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EXAMINER	
SMITH, STEPHANIE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,789	HETTRICK ET AL.	
	Examiner	Art Unit	
	Stephanie Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *27 September 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 27, 2004 was filed after the mailing date of the application on April 15, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 12-18, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehra et al (U.S. 6185459). Referring to claims 1-2, 12-13, and 23, Mehra et al. teach a pacemaker that delivers tachyarrhythmia prevention therapy for an extended period of time (see Abstract). The pacemaker can employ a metric to determine if therapy is successful. The metric measured can be the frequency of occurrence of PACs, and further may be a defined range of PACs per hour, determined by the physician to represent an acceptable range of occurrences of PACs. The aggressiveness of the atrial arrhythmia prevention pacing modality employed may be increased in response to the number of occurrences of PACs being in excess of the defined endpoint range (see column 4, lines 5-12 and lines 30-38).

Regarding claims 3 and 14, Mehra et al. teach that in response to an increase in PACs/day, the rate of the therapy may be increased (see column 21, lines 65-67 and column 22, lines 1-10). With reference to claims 4-5 and 15-16, Mehra et al. teach the device described above and further disclose that certain endpoints such as PACs/day and AF/day may be defined for a 24-hour period. Due to one or both of the PAC/day and AF/day values exceeding the defined acceptable ranges, the pacing parameters are adjusted to be more aggressive by either increasing or decreasing the rate. During a new 24-hour period, data is collected with the newly adjusted endpoints (see column 21, lines 57-67 and column 22, lines 1-15). With regards to claims 6-7 and 17-18, Mehra et al. disclose that the metric used to optimize the parameters of the arrhythmia prevention pacing modality may also be employed to disable the arrhythmia prevention pacing modality or to trigger the switch to an alternative pacing prevention modality (see column 4, lines 45-51). While not stated explicitly, it is inherent that arrhythmia detection subsequent to therapy is employed since the therapy is arrhythmia prevention pacing modality, and detecting an arrhythmia would prove the pacing to be ineffective.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-11 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra et al. Mehra et al. disclose the claimed invention except for determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method for controlling therapy in an implantable medical device as taught by Mehra et al, with determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold since it was known in the art that determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time

threshold is used to provide accurate and effective therapy and to prevent further damage to the patient.

Additionally, Mehra et al. disclose the claimed invention but do not disclose expressly the determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system and method for controlling therapy in an implantable medical device as taught by Mehra et al. with the determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold, because Applicant has not disclosed that determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with determining whether the second event is detected subsequent to delivery of therapy and determining whether therapy has been delivered for a predetermined time threshold (see figure 11), because it is used to provide accurate and effective therapy and to prevent further damage to the patient and since it appears to be an arbitrary design

consideration which fails to patentably distinguish over Mehra et al. Therefore, it would have been an obvious matter of design choice to modify Mehra et al. to obtain the invention as specified in the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Smith whose telephone number is 571-272-2834. The examiner can normally be reached on Monday-Friday between 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRS 7/24/06
SRS

GEORGE R. EVANISKO
PRIMARY EXAMINER
7/24/6